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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT / APPLICANT:	J. Paul GOLL
SERIAL NO.:	10/006,651
FILED:	December 10, 2001
FOR:	NEEDLE-LESS INJECTION APPARATUS AND METHOD
ART UNIT:	3763
EXAMINER:	M. Mendez

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PATENT & TRADEMARK OFFICE

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APPEAL BRIEF

In accordance with 37 C.F.R. § 41.37, Appellant respectfully submits this Appeal Brief, in triplicate. The Commissioner is authorized to charge the fee of $ 500.00 under 37 C.F.R. § 41.20(b)(2) to deposit account no. 11-0600.

REAL PARTY IN INTEREST

The real party in interest is Boston Scientific Scimed, Inc., assignee of this application. The inventor, J. Paul Goll, executed an assignment to Scimed Life Systems, Inc., which was recorded in the U.S. Patent & Trademark Office ("PTO") on February 7, 2000, at reel 010599, frame 0751. Effective January 1, 2005, Scimed Life Systems, Inc., changed its name to Boston Scientific Scimed, Inc. Documentation of that name change is being filed for recordation in the PTO.

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RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known to Appellant, Appellant's legal representative, or the assignee that are related to, will directly affect, will be directly affected by, or will have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 19 through 45 are pending, stand finally rejected, and are the subject of this appeal. These claims are reproduced in the Appendix to this Appeal Brief.

STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed December 14, 2004, making a change to claim 29. The Advisory Action dated January 11, 2005, indicated that this amendment would be entered for purposes of appeal.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention provides a device and method for making an injection into tissue inside a patient without the use of a needle. In various embodiments, the device and method provide different configurations of injection nozzles -- for example, with a piercing end, or with expanding or converging lumens -- and other mechanisms for improved injection -- such as a vacuum source to provide suction to anchor the injection end of the device against the tissue injection site.

An example of an injection catheter according to the invention is shown in Figures 1A and 1B. The injection catheter comprises a shaft having a proximal region (top left of Figure

1A), a distal region (shown enlarged in Figure 1B) and an infusion lumen 38 (Fig. 4) extending therethrough. A high pressure source 20 is in fluid communication with the infusion lumen 38. An injection port 30 is located at the distal region of the injection catheter and is in fluid communication with the infusion lumen 38.

In use, the distal end of the injection catheter is inserted into the patient, and the injection catheter is navigated until the distal region is positioned adjacent to an injection site. A high transient pressure is generated in the fluid at the pressurized fluid source, causing the pressurized fluid to pass through the infusion lumen and the injection port, and injecting the pressurized fluid into the tissue of the patient.

For purposes of this appeal, Appellant identifies the following six groups of claims, each of which is separately patentable:

Group I:	Claims 29 and 38-40;
Group II:	Claims 32, 34 and 41-43;
Group III:	Claim 44;
Group IV:	Claim 45;
Group V:	Claims 19-22, 25-28, 30-31, 33 and 35-37; and
Group VI:	Claims 23 and 24.

Group I: Claims 29 and 38-40

In Group I, claims 29 and 38 are independent. In claim 29, the distal region of the catheter has a nozzle and an injection port, and the claimed method includes the step of "penetrating a surface of the tissue with the injection port." In claim 38, the method includes the step of "penetrating the surface of target tissue by urging a piercing end of [the] medical device into the target tissue."

Claims 29 and 38 both embrace methods using the embodiments described in the specification as having a "sharpened" nozzle to penetrate tissue. The specification states:

> Nozzle 26 may be blunt or sharpened, depending on whether the injection port 30 is to be disposed adjacent to the heart tissue or partially penetrate the heart tissue.

Specification, page 9, lines 16-18.

With respect to the embodiments illustrated in Figures 6D and 6E, the specification further states:

> The distal end of the nozzle 26 may be blunt as illustrated in Figures 6A-6C or may be sharpened as illustrated in Figure 6D. The sharpened distal end of the nozzle 26D facilitates insertion of the distal end thereof partially into the heart tissue. In particular, the sharpened end of the nozzle 26D facilitates insertion of the injection port 30C just below the epicardial or endocardial surface of the heart, depending on the approach. ... [With respect to Figure 6E, once] the sharpened end of nozzle 26E penetrates the epicardial or endocardial surface of heart, the injection port(s) 30D/30E is/are positioned in the epicardial or endocardial space to deliver fluid therein.

Specification, page 12, lines 6-16.

> If the distal tip of the nozzle 26 is sharpened as illustrated in Figures 6D and 6E, the distal end of the injection catheter 24 is advanced a sufficient depth to position the injection port 26 just below the epicardial or endocardial surface.

Specification, page 14, lines 4-7.

Group II: Claims 32, 34 and 41-43

In Group II, claim 41 is independent. Claim 41 includes the step of "activating a vacuum force to urge the distal region of the catheter towards the target tissue and to temporarily stabilize the distal region of the catheter at the target tissue." Claims 32 and 34, both of which depend from claim 31, recite "a vacuum source in fluid communication with the annular lumen," wherein the annular lumen is formed between an inner surface of an outer sheath and an outer surface of the shaft.

In the embodiment illustrated in Figures 1A and 1B, a vacuum source 22 is shown. The vacuum source 22 is connected to draw suction through the annular space between the outer sheath 28 and the inner injection catheter 26. The outer sheath has a suction head 32 at its distal end.

The specification states:

> For application of suction, the inner lumen 36 of the outer sheath 28 is in fluid communication with the vacuum source 22. By actuating the vacuum source 22, suction is applied to the suction head 32 via the inner lumen 36. When the suction head 32 is positioned adjacent the heart tissue, the suction head 32 grasps the surface of the heart tissue thereby stabilizing the distal portion 18 of the catheter assembly 12.

Specification, page 10, lines 3-8.

As shown in Figure 7B, the vacuum maintains the position of the catheter during injection. The specification states:

> The suction head 32 grasps the surface of the heart tissue 60 upon application of a vacuum by a vacuum source 22. By grasping the surface of the heart tissue 60, the suction head 32 stabilizes the distal portion 18 of the catheter. This is particularly beneficial when treating tissue in a dynamic situation such as when the heart is beating. Absent a stabilizing means such as suction head 32, it may be difficult to maintain the distal portion 18 in a relatively fixed position relative to the heart tissue 60.

Specification, page 14, lines 13-19.

Group III: Claim 44

In Group III, claim 44 is independent. Claim 44 includes the limitation of "the distal end of the lumen having a reduced cross-sectional area when compared with the average cross-sectional area of the lumen."

An example of such a configuration is shown in Figure 6C. This configuration is described in the specification at page 12, lines 2-5.

Group IV: Claim 45

In Group IV, claim 45 is independent. Claim 45 includes the limitation of "the distal end of the lumen having an enlarged cross-sectional area when compared with the average cross-sectional area of the lumen."

An example of such a configuration is shown in Figure 6B. This configuration is described in the specification at page 11, line 23, to page 12, line 2.

Group V: Claims 19-22, 25-28, 30-31, 33, and 35-37

In Group V, claims 19 and 30 are independent. Both claim 19 and claim 30 require a "high transient pressure" that is generated in the fluid "at the pressurized fluid source" or at a "high pressure source," wherein the generated high transient pressure is "sufficient to pierce bodily tissue." With respect to the illustrated example, the specification states:

> The pressurized fluid source 20 preferably generates a pressure of approximately 5000 psi (peak) or more in less than 1 second in order to pierce the tissue at the treatment site. The pressurized fluid source 20 may generate a pressure in the range of 4000-7000 psi, and may be coupled to pressure and flow regulators to control the pressure and volume of fluid delivered through the catheter 12. The pressure range may be modified depending on the tissue characteristics, but must be sufficiently high to pierce the tissue.

Specification, page 8, lines 11-16.

Group VI: Claims 23 and 24

Both of the Group VI claims depend from claim 19. Claim 23 recites that "the high transient pressure reaches at least 5000 psi in less than about one second." Claim 24 recites that "the high transient pressure peaks between around 4000 psi and around 7000 psi." Specification, page 8, lines 11-16.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 19 through 45 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,641,553 to Chee et al. ("Chee") in view of U.S. Patent No. 6,056,716 to D'Antonio et al. ("D'Antonio").

For purposes of this appeal, the claims in each of the above-identified Groups I through VI stand or fall independently of the claims in the other groups. Accordingly, each of Groups I through VI is addressed separately below.

ARGUMENT

Group I: Claims 29 and 38-40

In claim 29, the distal region of the catheter has a nozzle and an injection port, and the claimed method includes the step of "penetrating a surface of the tissue with the injection port." In claim 38, the method includes the step of "penetrating the surface of target tissue by urging a piercing end of [the] medical device into the target tissue." As an example, such methods are practiced by a catheter having a "sharpened" nozzle. Embodiments include those illustrated in Figures 6D and 6E.

Appellants respectfully submit that the Chee and D'Antonio references, either alone or in combination, do not disclose or suggest the claimed invention. The Chee reference discloses a catheter assembly for needle-less injection wherein the distal end of the catheter has a distal-end face 26 with one or more narrow ports or orifices 28a-28d. Because the Chee reference is directed at overcoming the prior art problem of "tissue damage [that] can occur in the region of needle penetration" (1:45-46), the distal end of the Chee catheter has a "substantially blunt, distal-end face." Chee, 2:2 and 4:13-14. The Chee reference states that the catheter is advanced

until it is urged "against" -- not "into" -- the tissue. The Chee distal end creates a "contact" -- not "penetrating" -- force between the device and the tissue. Chee, 9:22-24.

The Chee reference specifically criticizes "penetration," because penetration of tissue can cause tissue damage. 1:45-46. Accordingly, the Chee reference directs a person of ordinary skill in the art away from the Appellant's claimed "penetrating" of the tissue surface, as claimed in claims 29 and 38.

In the Examiner's rejections, the Examiner has not addressed the limitations in Appellant's claims 29 and 38 of "penetrating a surface of the tissue with the injection port" and "penetrating the surface of target tissue by urging a piercing end of [the] medical device into the target tissue." The Examiner has not stated any motivation provided by the references for modifying the Chee reference to provide tissue penetration, nor is there any such motivation, particularly in view of the Chee reference's criticism of tissue penetration.

For the foregoing reasons, the Appellant respectfully submits that the rejection of claims 29 and 38-40 should be reversed.

Group II: Claims 32, 34 and 41-43

Claim 41 includes the step of "activating a vacuum force to urge the distal region of the catheter towards the target tissue and to temporarily stabilize the distal region of the catheter at the target tissue." Claims 32 and 34 both recite "a vacuum source in fluid communication with the annular lumen."

The Chee reference does not disclose a vacuum source or any suction force applied for stabilizing the distal end of the catheter. In addition, none of the other references of record provides any suggestion for modifying the Chee reference to include such a vacuum force.

In the Examiner's rejections, the Examiner has not addressed the limitations in Appellant's claims 41, 32 and 34 of "activating a vacuum force to urge the distal region of the

catheter towards the target tissue and to temporarily stabilize the distal region of the catheter at the target tissue" or "a vacuum source in fluid communication with the annular lumen." The Examiner has not stated any motivation provided by the references for modifying the Chee reference to provide for such a vacuum.

For the foregoing reasons, the Appellant respectfully submits that the rejection of claims 32, 34 and 41-43 should be reversed.

Group III: Claim 44

Claim 44 includes the limitation of "the distal end of the lumen having a reduced cross-sectional area when compared with the average cross-sectional area of the lumen."

The Chee reference discloses a lumen 22 that has a constant cross-section along its length. There is no suggestion that the lumen 22 of Chee should be modified to have a reduced cross-sectional area at its distal end.

In the Examiner's rejections, the Examiner has not addressed the limitation in Appellant's claim 44 of "the distal end of the lumen having a reduced cross-sectional area when compared with the average cross-sectional area of the lumen." The Examiner has not stated any motivation provided by the references for modifying the Chee reference to provide for such a reduced cross-sectional area at the distal end of the lumen.

For the foregoing reasons, the Appellant respectfully submits that the rejection of claim 44 should be reversed.

Group IV: Claim 45

Claim 45 includes the limitation of "the distal end of the lumen having an enlarged cross-sectional area when compared with the average cross-sectional area of the lumen."

As discussed above, the Chee reference discloses a lumen 22 that has a constant cross-section along its length. There is no suggestion that the lumen 22 of Chee should be modified to have an enlarged cross-sectional area at its distal end.

In the Examiner's rejections, the Examiner has not addressed the limitation in Appellant's claim 45 of "the distal end of the lumen having an enlarged cross-sectional area when compared with the average cross-sectional area of the lumen." The Examiner has not stated any motivation provided by the references for modifying the Chee reference to provide for such an enlarged cross-sectional area at the distal end of the lumen.

For the foregoing reasons, the Appellant respectfully submits that the rejection of claim 45 should be reversed.

Group V: Claims 19-22, 25-28, 30-31, 33, and 35-37

Claims 19 and 30 require a "high transient pressure" that is generated in the fluid "at the pressurized fluid source" or at a "high pressure source," wherein the generated high transient pressure is "sufficient to pierce bodily tissue."

In the Chee reference, the fluid is disclosed as gaining velocity for penetrating bodily tissue only after passing from the main lumen of the catheter through one or more narrow ports or orifices 28a-28d. The size of the orifices 28a-28d increases the fluid velocity, which, according to the Chee reference, is then sufficient to penetrate tissue.

In the Chee reference, the pressurized source for the fluid is described as being "operable to establish an elevated pressure (e.g., up to about 300 psi)" (2:7-9), which is far less than the pressures that would be "sufficient to pierce bodily tissue," as claimed in Appellant's claims 19 and 30.

The Examiner contends that it would have been obvious to provide higher source pressures to the Chee device in view of the D'Antonio reference. To be sure, the D'Antonio

reference mentions pressures up to 10,000 psi, just as there are likely numerous other references that describe high pressure systems with similar pressures. However, the mere disclosure of such high pressures does not provide any suggestion as to why such high pressures should be implemented in the Chee device, particularly when the Chee reference teaches away from such pressures. There is simply nothing in the disclosure of the D'Antonio reference that provides any suggestion of <u>why</u> a person of ordinary skill in the art would seek to use those pressures to substantially increase the pressures disclosed in the Chee reference, particularly the <u>source</u> pressure, in view of the fact that the Chee reference specifically identifies a much lower pressure limit in its example of "<u>up to</u> 300 psi." There is simply no reason provided for ignoring this disclosure in the Chee reference and instead providing <u>source</u> pressures that are "sufficient to pierce bodily tissue." The Chee reference itself teaches away from such pressures.

For the foregoing reasons, the Appellant respectfully submits that the rejection of claims 19-22, 25-28, 30-31, 33 and 35-37 should be reversed.

<u>Group VI: Claims 23 and 24</u>

Claim 23 recites that "the high transient pressure reaches at least 5000 psi in less than about one second." Claim 24 recites that "the high transient pressure peaks between around 4000 psi and around 7000 psi." Specification, page 8, lines 11-16.

The Examiner points to the fact that the D'Antonio reference mentions pressures as high as 2,000 to 10,000 psi. As discussed above, the mere disclosure of such high pressures does not provide any suggestion as to why such high pressures should be implemented in the Chee device, particularly when the Chee reference teaches away from such pressures, specifically identifying a much lower upper limit in its example of "<u>up to</u> 300 psi."

For the foregoing reasons, the Appellant respectfully submits that the rejection of claims 23 and 24 should be reversed.

* * *

For the foregoing reasons, the Appellant respectfully requests favorable consideration by the Board of this appeal and reversal of the final rejection of claims 19 through 45.

The Office is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 or §1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

Date: Apr. 11, 2005

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APPENDIX

19. A method of delivering a fluid to tissue of a patient, comprising:

providing a pressurized fluid source;

providing an injection catheter comprising a shaft having a proximal region, a distal region and an infusion lumen extending therethrough, the distal region of the catheter including a nozzle and an injection port, the proximal region of the catheter fluidly coupled to the pressurized fluid source;

inserting the injection catheter into the patient;

navigating the injection catheter until the distal region is positioned adjacent to an injection site;

generating a high transient pressure in the fluid at the pressurized fluid source, the high transient pressure sufficient to pierce bodily tissue; and

injecting the pressurized fluid into the tissue of the patient by causing the pressurized fluid to pass through the infusion lumen and the injection port.

20. The method of claim 19 wherein the smallest cross-sectional area of the injection port is at least one-third of the cross-sectional area of the infusion lumen when measured at the beginning of the transition from the infusion lumen to the nozzle.

21. The method of claim 19 wherein the transient pressure of the fluid within the lumen is sufficient to pierce tissue prior to the fluid passing through the injection port.

22. The method of claim 19 wherein the injection port is defined by surfaces of the infusion lumen.

23. The method of claim 19 wherein the high transient pressure reaches at least 5000 psi in less than about one second.

24. The method of claim 19 wherein the high transient pressure peaks between around 4000 psi and around 7000 psi.

25. The method of claim 19 further comprising regulating a fluid flow through the catheter.

26. The method of claim 25 wherein the regulating step includes drawing a vacuum force through the catheter.

27. The method of claim 19 further comprising regulating a volume of the fluid injected through the injection port.

28. The method of claim 19 further comprising stabilizing the distal region of the catheter adjacent to the injection site by creating a fluid seal between the tissue and the distal region of the catheter.

29. A method of delivering a fluid to tissue of a patient, comprising:

providing an injection catheter comprising a shaft having a proximal region, a distal region and an infusion lumen extending therethrough, the distal region of the catheter including a nozzle and an injection port;

inserting the injection catheter into the patient;

navigating the injection catheter until the distal region is positioned adjacent to an injection site;

penetrating a surface of the tissue with the injection port; and

forcing fluid out of the injection port and into the penetrated tissue, the fluid forced into the tissue being under a pressure sufficient to pierce the tissue.

30. A catheter for delivering fluid to tissue of a patient, comprising:

an injection catheter comprising a shaft having a proximal region, a distal region and an infusion lumen extending therethrough;

a high pressure source in fluid communication with the infusion lumen, the high pressure source adapted to generate a high transient pressure in fluid exiting the high pressure source, the pressure of the exiting fluid being sufficient to pierce bodily tissue; and

an injection port at the distal region of the injection catheter in fluid communication with the infusion lumen.

31. The catheter of claim 30 further comprising an outer sheath coaxially disposed around the shaft wherein an annular lumen is formed between an inner surface of the outer sheath and an outer surface of the shaft.

32. The catheter of claim 31 further comprising a vacuum source in fluid communication with said annular lumen wherein when the distal end of the injection catheter is placed in contact with the tissue and a vacuum is applied to the annular lumen, the distal end of the injection catheter is stabilized against the tissue.

33. The catheter of claim 30 wherein the means for generating high transient pressure in the fluid comprises a syringe containing the fluid.

34. The catheter of claim 31 further comprising a vacuum source in fluid communication with the annular lumen.

35. The catheter of claim 33, wherein the syringe is actuated pneumatically.

36. The catheter of claim 30, wherein the means for generating high transient pressure in the fluid is an automated high pressure injection system.

37. The catheter of claim 30 wherein the means for generating a high transient pressure in a fluid is a transdermal injection device.

38. A method of delivering a liquid to target tissue at a target site of a patient, comprising:

penetrating the surface of target tissue by urging a piercing end of a medical device into the target tissue, the medical device having a lumen in fluid communication with a source of the liquid; and

piercing tissue at the target site by forcing liquid out of the piercing end of the medical device after the medical device has penetrated the surface of the target tissue, the liquid exiting the medical device having a transient pressure sufficient to pierce tissue at the target site.

39. The method of claim 38 wherein the piercing end of the medical device terminates in a pointed ridge.

40. The method of claim 38 wherein the piercing end of the medical device defines orifices opening in a direction orthogonal to the lumen in the medical device.

41. A method of delivering a liquid to a target tissue comprising:

placing the distal region of a catheter at a target tissue site;

activating a vacuum force to urge the distal region of the catheter towards the target tissue and to temporarily stabilize the distal region of the catheter at the target tissue; and

ejecting liquid from the catheter under such pressure that the liquid pierces the target tissue.

42. The method of claim 41 wherein the catheter contains a first lumen and a second lumen, the first lumen transmitting a vacuum force to the distal region of the catheter and the second lumen transmitting the liquid to the distal region of the catheter.

43. The method of claim 42 wherein the first lumen of the catheter is enlarged at its distal region.

44. A medical device for delivering high pressure fluids to a target site, the medical device comprising:

a lumen ending in a distal end; and

a pressure source in fluid communication with the lumen, the pressure source adapted to place liquid in the lumen under a high transient pressure sufficient to pierce tissue,

the distal end of the lumen having a reduced cross-sectional area when compared with the average cross-sectional area of the lumen.

45. A medical device for delivering high pressure fluids to a target site, the medical device comprising:

a lumen ending in a distal end; and

a pressure source in fluid communication with the lumen, the pressure source adapted to place liquid in the lumen under a high transient pressure sufficient to pierce tissue,

the distal end of the lumen having an enlarged cross-sectional area when compared with the average cross-sectional area of the lumen.